



**MOLBIO DIAGNOSTICS PVT. LTD.**

**An ISO 9001 & ISO 13485 certified company**

**CERTIFICATE OF ANALYSIS**

**Mfg. Lic. No. : 874/L**

**Date 15/06/2019**

**PRODUCT : Truenat™ MTB**

**LOT. NO. : TB101**

**MFG. DATE : 2019- 06**

**EXP. DATE : 2021- 05**

**PACK SIZE : 5T, 20T**

**STORAGE : 2°C to 30°C**

**A.R. No. : B-TB-101a**

**PRECAUTION:** The product is offered without warranty for any other specific use than that specified in the Instructions for Use.

Sr. No.	Components in each kit	Specification	Observation
1	Pouch contains 1 chip, 1 micro tube, 1 desiccant pouch and 1 filter barrier tip	5 nos., 20 nos.	Pass
2	Colour of desiccant pouch	Blue	Pass
3	Package insert	01 no.	Pass

Performance CONTROLS			
Sr. No.		Test Lot (Ct Values)	
		MTB	Control
Specificity Tests			
Negative Control		ND	27.75
		ND	26.2
Positive Control		29	28.8
		29.67	28
		30.14	28
		29.17	27.5
		30.17	30.17
		30.8	31.57
		29.5	28.6
		30.33	29.25
Standard deviation		± 0.62	± 1.34

\*ND- Not detected

\*A deviation of  $\leq 1.5$  is acceptable for Ct values

**MANUFACTURING RECORDS ARE VERIFIED, CHECKED AND PRODUCT IS MANUFACTURED AS PER THE MASTER FORMULA, SAMPLES TESTED AND LOT IS RELEASED FOR SALE**

**QUALITY CONTROL**  
Name: Dr. Praveen Kumar  
Designation: QC Head

**Molbio Diagnostics Pvt. Ltd.**

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